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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/752,656	12/29/2000	Beth C. Munoz	00140	9394

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EXAMINER	
SINES, BRIAN J	

ART UNIT	PAPER NUMBER
1743	

MAIL DATE	DELIVERY MODE
09/25/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/752,656	MUNOZ ET AL.	
	Examiner	Art Unit	
	Brian J. Sines	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *4/6/2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40 and 42-57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8-27,29-40,42-45,47-53 and 55-57* is/are rejected.

7)☒ Claim(s) *7,28,46 and 54* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/6/2007 has been entered.

Response to Arguments

Applicant's arguments with respect to the present claims have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3 – 5, 8 – 11, 42 – 45, 47 – 53 and 55 – 57 are rejected under 35 U.S.C. 102(b) as being anticipated by Maley et al. (U.S. Pat. No. 5,770,028 A).

Regarding claims 1, 3, 10, 42 – 45, 47 – 53 and 55 – 57, Maley et al. teach an electrochemical sensing apparatus comprising: conductive modified particles, such as electrically-conducting carbon or graphite powder particles, having at least one organic group attached, such as an immobilized enzyme, to the particles (see col. 14, lines 12 – 50). Maley et al. anticipates that an enzyme may be immobilized directly or covalently

bonded to the carbon or graphite particles via the incorporation of organic functional groups. Bennetto et al. (U.S. Pat. No. 4,970,145) is incorporated by reference with Maley (see col. 14, lines 12 – 32). Bennetto et al. teach the immobilization of an enzyme on the surface of carbon substrate using well established covalent immobilization techniques (see, e.g., col. 7, line 63 – col. 8, line 65). Maley et al. do teach that any suitable carbon or graphite powder, which readily permits the subsequent immobilization of an enzyme may be used to form the active layer. The carbon particles do comprise organic functional groups, such as carboxylate, amino and sulfur-containing functional groups, on their surface (see col. 14, lines 41 – 50). Maley et al. do teach the use of an electrical measuring apparatus for performing sensor response measurements (see col. 27, lines 50 – 61). Regarding product and apparatus claims, when the structure recited in the reference is substantially identical to that of the claims, claimed properties or functions are presumed to be inherent (see MPEP § 2112.01). The Courts have held that it is well settled that where there is a reason to believe that a functional characteristic would be inherent in the prior art, the burden of proof then shifts to the applicant to provide objective evidence to the contrary. See *In re Schreiber*, 128 F.3d at 1478, 44 USPQ2d at 1478, 44 USPQ2d at 1432 (Fed. Cir. 1997).

Regarding claims 4, 5, 9 and 11, Maley et al. teach the use of carbon black materials, which are well known in the art to be pigment materials (see col. 15, lines 11 – 21) (see MPEP § 2144.03). Maley et al. teach that the carbon particles may comprise a metal substrate layer coating comprising platinum (see col. 14, lines 51 – 64). Regarding claim 8, Maley et al. teach an aggregate comprising a carbon phase (e.g., carbon black or graphite particles) and a metal-containing phase (e.g., finely divided platinum group

metal either deposited or adsorbed onto the carbon or graphite particles) (see col. 14, lines 12 – 50).

As discussed above, Maley et al teach all of the positively recited structural limitations of the claimed apparatus. The Courts have held that a statement of intended use in an apparatus claim fails to distinguish over a prior art apparatus. See *In re Sinex*, 309 F.2d 488, 492, 135 USPQ 302, 305 (CCPA 1962). The Courts have held that the manner of operating an apparatus does not differentiate an apparatus claim from the prior art, if the prior art apparatus teaches all of the structural limitations of the claim. See *Ex Parte Masham*, 2 USPQ2d 1647 (BPAI 1987). Furthermore, the Courts have held that apparatus claims must be structurally distinguishable from the prior art in terms of structure, not function. See *In re Danley*, 120 USPQ 528, 531 (CCPA 1959); and *Hewlett-Packard Co. V. Bausch and Lomb, Inc.*, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (see MPEP § 2114).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 1, 3 – 5, 8 – 11, 42 – 45, 47 – 53 and 55 – 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maley et al. in view of Bennetto et al.

Regarding claims 1, 3 and 10, Maley et al. teach an electrochemical sensing apparatus comprising: conductive modified particles, such as electrically-conducting carbon or graphite powder particles, having at least one organic group attached, such as an immobilized enzyme, to the particles (see col. 14, lines 12 – 50). Maley et al. anticipates that an enzyme may be immobilized directly or covalently bonded to the carbon or graphite particles via the incorporation of organic functional groups. Bennetto et al. (U.S. Pat. No. 4,970,145) is incorporated by reference with Maley (see col. 14, lines 12 – 32). Bennetto et al. teach the immobilization of an enzyme on the surface of carbon substrate using well established covalent immobilization techniques (see, e.g., col. 7, line 63 – col. 8, line 65). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate a covalently bonded organic group with the conductive modified particles as claimed. Maley et al. do teach that any suitable carbon or graphite powder, which readily permits the subsequent immobilization of an enzyme may be used to form the active layer. The carbon particles do comprise organic functional groups, such as carboxylate, amino and sulfur-containing functional groups, on their surface (see col. 14, lines 41 – 50). Maley et al. do teach the use of an electrical measuring apparatus for performing sensor response measurements (see col. 27, lines 50 – 61). Regarding product and apparatus claims, when the structure recited in the reference is substantially identical to that of the claims, claimed properties or functions are presumed to be inherent (see

MPEP § 2112.01). The Courts have held that it is well settled that where there is a reason to believe that a functional characteristic would be inherent in the prior art, the burden of proof then shifts to the applicant to provide objective evidence to the contrary. See *In re Schreiber*, 128 F.3d at 1478, 44 USPQ2d at 1478, 44 USPQ2d at 1432 (Fed. Cir. 1997).

Regarding claims 4, 5, 9 and 11, Maley et al. teach the use of carbon black materials, which are well known in the art to be pigment materials (see col. 15, lines 11 – 21) (see MPEP § 2144.03). Maley et al. teach that the carbon particles may comprise a metal substrate layer coating comprising platinum (see col. 14, lines 51 – 64).

Regarding claim 8, Maley et al. teach an aggregate comprising a carbon phase (e.g., carbon black or graphite particles) and a metal-containing phase (e.g., finely divided platinum group metal either deposited or adsorbed onto the carbon or graphite particles) (see col. 14, lines 12 – 50).

Regarding claims 2, 22 – 25 and 31, Maley et al. do not specifically teach an array of sensors, wherein the array comprises two or more sensors. However, the Courts have held that the mere duplication of parts, without any new or unexpected results, is within the ambit of one of ordinary skill in the art. See *In re Harza*, 124 USPQ 378 (CCPA 1960) (see MPEP § 2144.04). Furthermore, the use of sensing devices incorporating the use of a plurality of sensors arranged in an array configuration are notoriously well known in the art (see MPEP § 2144.03). In addition, the Courts have held that the prior art can be modified or combined to reject claims as *prima facie* obvious as long as there is a reasonable expectation of success. See *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986) (see MPEP § 2143.02). As a result, a person of ordinary skill in the art would accordingly have had a reasonable expectation of success of

incorporating a plurality of sensors within such a sensing apparatus, as taught by Maley et al. Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate an array of sensors within the sensing apparatus, as taught by Maley et al., in order to facilitate, for example, the detection and monitoring of a plurality of different chemical species within an environment.

Regarding claims 22, 26, 29 and 32, Maley et al. teach the use of carbon black materials, which are well known in the art to be aggregated pigment materials (see col. 15, lines 11 – 21) (see MPEP § 2144.03).

Regarding claim 30, Maley et al. teach that the carbon particles may further comprise a metal substrate layer coating comprising platinum (see col. 14, lines 51 – 64).

Regarding claims 33 – 37, enzymes are proteinaceous materials composed of polymeric peptides well known in the art to comprise various functional organic groups, such as aromatic and ionic groups (see MPEP § 2144.03).

2. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Maley et al. and Bennetto et al. in view of Dai et al. (U.S. Pat. No. 6,528,020 B1).

Regarding claim 6, Maley et al. do not specifically teach the incorporation of carbon nanotubes for sensing. Dai et al. do teach the use of carbon nanotubes in a biological sensor, wherein biological molecules, such as an enzyme, can be attached to the nanotube (see col. 5, lines 32 – 43). Dai et al. do recognize that there is a need in the art for sensing devices that provide not only significant and robust, but more advantageously, tunable response to a variety of chemical and biological species (see col. 1, lines 24 – 65). In addition, both of the disclosures of Dai et al. and Maley et al. are directed to sensing devices for detecting glucose. Both of the sensors disclosed by Maley

et al. and Dai et al. function in a similar manner based upon using an electrochemical response (see Dai et al., col. 6, lines 1 – 6 & Maley et al., col. 1, lines 1 – 13). Consequently, a person of ordinary skill in the art would have recognized the suitability of incorporating the teachings of Dai et al. with the sensing apparatus of Maley et al./Bennetto et al. for the intended purpose of facilitating the effective sensing operation of a biological sensor (see MPEP § 2144.07). Furthermore, the Courts have held that the prior art can be modified or combined to reject claims as *prima facie* obvious as long as there is a reasonable expectation of success. See *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986) (see MPEP § 2143.02). As evidenced by Dai et al., carbon nanotubes can be effectively utilized in a biological sensor, wherein the carbon nanotubes have organic or biological molecules, such as an enzyme, attached to the nanotube (see col. 5, lines 32 – 67 & col. 6, lines 1 – 17). Hence, a person of ordinary skill in the art would accordingly have had a reasonable expectation of success in employing the teachings of Dai et al. regarding the use of carbon nanotubes with a biological sensing device, as taught by Maley et al. Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate the use of a carbon nanotube, as taught by Dai et al., with the sensing apparatus, as taught by Maley et al., in order to facilitate effective detection.

3. Claims 1 – 3, 6, 10, 12 – 24, 27, 31 and 33 – 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lewis et al. (U.S Pat. No. 5,571,401) in view of Dai et al. (U.S. Pat. No. 6,528,020 B1) and Bennetto et al.

Regarding claims 1 – 3, 6, 10, 22 – 24, 27 and 31, Lewis et al. teach a sensing apparatus comprising: a first and second sensor electrically connected to an electrical

measuring apparatus, wherein the first sensor comprises a region of nonconducting organic polymer material and a region comprising conductive particles, such as carbonaceous materials (e.g., carbon blacks, graphite, etc.); and an electrical path through the regions of nonconducting material and conductive particles (see col. 3, lines 36 – 67 & col. 4, lines 1 – 65). Lewis et al. do teach the incorporation of an electrical measuring apparatus for performing sensor response measurements based upon electrical resistance (see, e.g., col. 3, lines 24 – 66; col. 7, lines 40 – 57). Lewis et al. do not specifically teach that the conductive modified particles comprise carbon products having at least one organic group attached to the particles.

Dai et al. do teach the use of carbon nanotubes, which is considered a carbon product, in electrochemical sensors. Dai et al. do recognize that there is a need in the art for sensing devices that provide not only significant and robust, but more advantageously, tunable response to a variety of chemical and biological species (see col. 1, lines 24 – 65). Dai et al. further teach that the nanotubes can be physically or chemically modified, so as to be tailored for a particular sensing application. Dai et al. teach that sensing agents can be deposited onto the nanotubes so that sensitivity to a wide range of chemical species can be achieved (see col. 4, line 66 – col. 5, line 6). Dai et al. teach a sensing apparatus comprising: conductive modified particles (carbon nanotubes, which are considered to be a carbon product), having at least one organic group attached, such as an immobilized enzyme, to the particles (see col. 5, lines 32 – 63 & col. 6, lines 1 – 11). Furthermore, Bennetto et al. teach the immobilization of an enzyme on the surface of carbon substrate using well established covalent immobilization techniques (see, e.g., col. 7, line 63 – col. 8, line 65). The Courts have held that the selection of a known material

based upon its suitability for the intended use is within the ambit of one of ordinary skill in the art. See *In re Leshin*, 125 USPQ 416 (CCPA 1960) (see MPEP § 2144.07). Furthermore, the Courts have held that the prior art can be modified or combined to reject claims as *prima facie* obvious as long as there is a reasonable expectation of success. See *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986) (see MPEP § 2143.02). As evidenced by Dai et al., organic polymers can be attached or deposited onto the nanotubes and thereby serve as effective sensing agents (see col. 6, lines 1 – 16). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate the teachings of Dai et al. with the sensing apparatus of Lewis et al.

Regarding claims 12, 13, 15, 16, 33, 34, 36 and 37, Dai et al. teach the incorporation of various polymers, such as polymethylmethacrylate, or biomolecules, such as enzymes, which are well known in the art to be proteinaceous materials comprising various organic functional groups (see col. 5, lines 43 – 50 & col. 6, lines 1 – 11) (see MPEP § 2144.03).

Regarding claims 14 and 35, Dai et al. teach the incorporation of a thiol functional group (see col. 5, lines 33 – 63).

Regarding claim 17, Lewis et al. teach that each sensor provides a different response for the same analyte with a detector that is operatively associated with each sensor (see col. 7, lines 3 – 58). Regarding claim 18, Lewis et al. teach that the sensing elements for each sensor are compositionally different from each other (see col. 3, lines 40 – 48; col. 6, lines 9 – 28).

Regarding claims 19 – 21 and 38 – 40, as discussed above, Lewis et al. in view of Dai et al. teach all of the positively recited structure of the apparatus recited in the

claimed method, which merely recites the conventional operation of that structure. Furthermore, Lewis et al. do teach that the method and apparatus essentially comprise a means for comparing the response with a library of responses to match the response in order to determine the presence of an analyte or the concentration of the analyte (see col. 7, line 23 – col. 8, line 17). Therefore, it would have been obvious to a person of ordinary skill in the art to perform the method recited in the instant claims upon the apparatus of Lewis et al. in view of Dai et al., as such is the intended operation of that apparatus.

4. Claims 25, 26 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lewis et al. in view of Dai et al., and further in view of Foulger et al. (U.S. Pat. No. 6,315,956 B1).

Regarding claim 25, Lewis et al. do teach the incorporation of carbon black, as a particulate conductive or conductive filler material, within the matrix of nonconductive organic polymer material comprising the sensing material (see col. 3, line 40 – col. 4, line 34). However, Neither Lewis et al. nor Dai et al. specifically teach that the conductive particles comprise carbon black having attached at least one organic group. Foulger et al. do teach the use of conductive filler materials comprising, inter alia, carbon black and carbon nanotubes, within an electrochemical sensor, in which the sensitivity and dynamic range of the electrochemical sensor is highly dependent on the conductive filler material. Foulger et al. teach that the conductive filler material may be any suitable material exhibiting conductivity and should have a structure which results in an inherently high conductivity with an affinity to develop a strong network (see col. 10, lines 10 – 67). The Courts have held that the selection of a known material, which is based upon its

suitability for the intended use, is within the ambit of one of ordinary skill in the art. See *In re Leshin*, 125 USPQ 416 (CCPA 1960) (see MPEP § 2144.07). Furthermore, a person of ordinary skill in the art would have recognized the functional equivalence of carbon black and carbon nanotube materials, as a particulate conductive or filler material used in sensing applications (see MEP § 2144.06). The Courts have held that an express suggestion to substitute one equivalent component or process for another is not necessary to render such a substitution obvious. See *In re Fout*, 675 F.2d 297, 213 USPQ 532 (CCPA 1982). Therefore, it would have been obvious to a person of ordinary skill in the art to substitute and incorporate the known equivalent carbon black material, as taught by Foulger et al., having an attached organic group, as taught by Dai et al., with the sensing apparatus of Lewis et al. in order, for example, to provide for effective sensing operation.

Regarding claim 26, it is well known in the art that carbon black is a pigment material (see MPEP § 2144.03).

Regarding claim 30, Dai et al. teach that the carbon nanotubes may be coated with metal particles, which impart sensitivity to a particular chemical species (see col. 2, lines 28 – 32). In view of the discussion above with respect to the recognized functional equivalence among carbon black and carbon nanotube materials as is generally known in the art, it would have been obvious to a person of ordinary skill in the art to incorporate conductive particles comprising at least partially coated carbon black materials within the sensing apparatus in order to provide for optimal sensor operation for a particular sensing application.

5. Claims 1, 3, 6 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dai et al. (U.S. Pat. No. 6,528,020 B1) in view of Bennetto.

Regarding claims 1, 3, 6 and 10, Dai et al. teach a sensing apparatus comprising: conductive modified particles (carbon nanotubes, which are considered to be a carbon product), having at least one organic group attached, such as an immobilized enzyme, to the particles (see col. 5, lines 32 – 63 & col. 6, lines 1 – 11). Bennetto et al. teach the immobilization of an enzyme on the surface of carbon substrate used in a sensing device using well established covalent immobilization techniques (see, e.g., col. 7, line 63 – col. 8, line 65). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate the use of the disclosed covalent immobilization techniques for facilitating effective immobilization . Dai et al. further teach the incorporation of an electrical measuring apparatus for performing sensor response measurements (see figures 4 – 8; col. 5, lines 17 – 67).

Allowable Subject Matter

Claims 7, 28 46 and 54 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter:

Regarding claims 7, 28 46 and 54, the cited prior art neither teach nor fairly suggest that the conductive modified particles comprise an aggregate comprising a carbon phase and a silicon-containing species phase, wherein the aggregate optionally has attached at least one organic group.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Sines, whose telephone number is (571) 272-1263. The examiner can normally be reached on Monday - Friday (11:30 AM - 8 PM EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BRIAN SINES
PRIMARY EXAMINER